Corporate Medical Policy: Beremagene geperpavec-svdt (Vyjuvek®) **"Notification"** **POLICY EFFECTIVE APRIL 1, 2026**

Restricted Product(s):

- beremagene geperpavec-svdt (Vyjuvek®) biological suspension mixed with excipient gel for topical administration

FDA Approved Use:

- For the treatment of wounds in adult and pediatric patients (from birth) with dystrophic epidermolysis bullosa with mutation(s) in the *collagen type VII alpha 1 chain* (*COL7A1*) gene

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

Initial Criteria for Approval:

1. The patient has a diagnosis of **dystrophic epidermolysis bullosa [medical record documentation required]**; **AND**
2. The diagnosis has been confirmed by ONE of the following **[medical record documentation required]**:
    a. Immunofluorescence mapping (IFM); **OR**
    b. Transmission electron microscopy (TEM); **OR**
    c. Genetic testing confirming presence of mutation(s) in the *collagen type VII alpha 1 chain* (*COL7A1*) gene; **AND**
3. The patient has at least one cutaneous wound that is clean in appearance with adequate granulation tissue, has excellent vascularization, and does not appear infected **[medical record documentation required]**; **AND**
4. The patient does NOT have current evidence or history of squamous cell carcinoma in the area undergoing treatment **[medical record documentation required]**; **AND**
5. The patient does NOT have an active infection in the area undergoing treatment **[medical record documentation required]**; **AND**
6. The patient will NOT be using the requested agent in combination with Filsuvez (birch triterpenes) or another gene therapy on the same treatment area for the requested indication **[medical record documentation required]**; **AND**
7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **[medical record documentation required]**; **AND**
8. The requested dose is within FDA labeled dosing for the requested indication, and the requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below) **[medical record documentation required]**; **AND**
9. For requests for administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval: 180 days (6 months)

Continuation Criteria for Approval:

1. The patient was approved through Blue Cross NC initial criteria for approval; **OR**
2. The patient would have met initial criteria for approval at the time they started therapy; **AND**
3. The patient has had clinical benefit with the requested agent as demonstrated by improvement in wound healing and/or complete wound closure **[medical record documentation required]**; **AND**
4. The patient continues to have at least one incomplete wound closure that is clean in appearance with adequate granulation tissue, has excellent vascularization, and does not appear infected **[medical record documentation required]**; **AND**
5. The patient does NOT have current evidence or history of squamous cell carcinoma in the area undergoing treatment **[medical record documentation required]**; **AND**
6. The patient does NOT have an active infection in the area undergoing treatment **[medical record documentation required]**; **AND**
7. The patient will NOT be using the requested agent in combination with Filsuvez (birch triterpenes) or another gene therapy on the same treatment area for the requested indication **[medical record documentation required]**; **AND**
8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **[medical record documentation required]**; **AND**
9. The requested dose is within FDA labeled dosing for the requested indication, and the requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below) **[medical record documentation required]**; **AND**
10. For requests for administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

    Duration of Approval: 365 days (1 year)

Please note, for certain identified gene and cellular therapies such as beremagene geperpavec-svdt (Vyjuvek®), when coverage is available and the individual meets medically necessary criteria, distribution from a specialty pharmacy provider due to cost (distribution channel restriction) may be required in order for coverage to be provided. **Please contact Blue Cross NC to coordinate this therapy.

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
beremagene geperpavec-svdt (Vyjuvek®) biological suspension mixed with excipient gel for topical application	Treatment of wounds in adult and pediatric patients with dystrophic epidermolysis bullosa with mutation(s) in the *COL7A1* gene	For topical application only. Apply gel once a week to selected wound(s) in droplets spaced evenly within the wound, approximately 1cm-by-1cm apart. See prescribing information for reference on dose per approximate size of wound. • < 3 years of age: Maximum weekly dose of 2 x 10^9 plaque forming units (PFU); maximum weekly volume of 1 mL • ≥ 3 years of age: Maximum weekly dose of 4 x 10^9 PFU; maximum weekly volume of 2 mL	J3401	Initial: 650 Continuation: 1,300

***Maximum units allowed for duration of approval**

Other revenue codes that may be applicable to this policy: 0891, 0892

***Site of Care Medical Necessity Criteria**

1. For requests for administration in an **inpatient setting**, the requested medication may be given if the above medical necessity criteria are met AND the inpatient admission is NOT for the sole purpose of administering the requested medication; **OR**
2. For requests for administration in an **outpatient hospital setting**, the requested medication may be given if the above medical necessity criteria are met AND ONE of the following must be met:
    a. History of a severe adverse event following the injection or infusion of the requested medication (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure); **OR**

   b. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access); **OR**
   c. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**
   d. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
   e. New to therapy, defined as initial administration OR less than 3 months since initial administration; **OR**
   f. Re-initiation of therapy, defined as ONE of the following:
      i. First administration after 6 months of no administrations for drugs with an approved dosing interval less than 6 months duration; **OR**
      ii. First administration after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; **OR**
   g. Requirement of a change in the requested restricted product formulation; **AND**
3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the requested medication will be administered in a **home-based** or physician office setting with or without supervision by a certified healthcare professional.

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Gurevich I, Agarwal P, Zhang P, et al. In vivo topical gene therapy for recessive dystrophic epidermolysis bullosa: a phase 1 and 2 trial. *Nat Med*. 2022 Apr;28(4):780-788. Epub 2022 Mar 28.
2. Has C, Liu L, Bolling MC, et al. Clinical practice guidelines for laboratory diagnosis of epidermolysis bullosa. *Br J Dermatol*. 2020 Mar;182(3):574-592.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q1 annually.

April 2026: Coding change: Added the following applicable revenue codes associated with policy HCPCS code(s): 0891 (Special Processed Drugs – FDA Approved Cell Therapy) and 0892 (Special Processed Drugs – FDA Approved Gene Therapy). **Policy notification given 2/1/2026 for effective date 4/1/2026**.
October 2025 v2: Criteria change: Minor updates made to formatting with no change to intent. Adjusted maximum units for clarity.
October 2025: Criteria change: Removed specific age criterion point due to expanded age of pediatric patients (from birth) and increased maximum weekly units, according to updated FDA labeling. Updated Site of Care medical necessity criteria to add additional bypass for patients with a history of severe adverse events or conditions that cause an increased risk for severe adverse event to align with the Place of Service for Medical Infusions policy for clarity of intent.

May 2025: Criteria change: Removed requirement within both initial and continuation sections that the patient has no serum antibodies to type VII collagen and no evidence of systemic infection. Removed requirement of no prior gene or cellular therapy for the requested indication within initial section. Added requirement within initial and continuation sections that the patient will not be using Vyjuvek in combination with Filsuvez (birch triterpenes) or another gene therapy on the same treatment area for the requested indication. Adjusted site of care criteria verbiage to be more applicable to topical administration for clarity with no change to intent.
January 2024: Coding change: Added HCPCS code J3401 to dosing reference table effective 1/1/2024; deleted C9399, J3490, and J3590 termed 12/31/2023. Adjusted maximum units according to coding unit definition for clarity.
June 2023: Original medical policy criteria issued.